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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,043	02/17/2004	Elizabeth Bates	SF0977XB	1489

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PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
DAHLE, CHUN WU	
ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,043	BATES ET AL.	
	Examiner	Art Unit	
	CHUN DAHLE	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9,18 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,9,18 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment to the claims, filed on September 18, 2009, is acknowledged.

Claims 1-6, 8, 10-17, 19-24, and 26-31 have been canceled.

Claims 7, 9, 18, and 25 are pending and currently under consideration.

2. This Office Action will be in response to applicant's arguments, filed on September 18, 2009.

The rejections of record can be found in the previous Office Actions, mailed on February 22, 2006, July 17, 2006, November 20, 2006, August 9, 2007, February 5, 2008, and August 14, 2008, and March 31, 2009.

3. Applicant's Remarks regarding the priority issues filed on September 18, 2009, is acknowledged. Applicant argues that the instant FDF03-S1 polypeptide consisting amino acid sequence of SEQ ID NO:6 is disclosed as SEQ ID NO:4 in priority document USSN 09/224,604. The examiner agrees with applicant's convincing assertion. As such, the prior rejection under 35 U.S.C. 102(b) based upon Adema et al. (WO 98/24906) as evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586.) and Bendayan (J. Histochem. Cytochem. 1995; 43:881-886.) has been withdrawn.

4. In view of applicant's convincing argument regarding that Lal et al. (US 2005/0155089) is not an appropriate 102(e) type reference because the PCT/US99/14484 in the continuity chain of Lal et al. is filed before November 29, 2000, the prior rejection under 35 U.S.C. 102(e) based upon Lal et al. (US 2005/0155089) has been withdrawn.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 7, 9, 18, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7, 9, 18, and 25 are indefinite in the recitation of "A purified antibody or fragment thereof….., wherein said antibody or fragment thereof is in complex with said FDF03-S1 polypeptide" because the metes and bounds of the wherein clause is unclear and ambiguous. The preamble of the claims appears to encompass a single entity of a purified antibody or fragment thereof. However, the wherein clause requires the presence of a complex that contains both the antibody and the antigen. Applicant's Remarks, filed on September 18, 2009, argue that the wherein clause limit the claims to a particular structure of a complex (e.g. see page 4 of the Remarks, filed on September 18, 2009). As such, it is not clear the subject matter that is being claimed. If applicant regards the antibody/antigen complex as his invention, applicant should claim the complex in the preamble of the claims.

For examination purposes, claims 7, 9, 18, and 25 are read as a purified antibody or fragment thereof instead of a complex containing antibody and antigen.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 7, 9, 18, and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Adema et al. (WO 98/24906, cited in IDS filed 02/17/04) as evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586, reference listed on PTO-892 mailed on February 22, 2006) and Bendayan (J. Histochem. Cytochem. 1995; 43:881-886, reference listed on PTO-892 mailed on February 22, 2006).

Adema et al. teach an isolated polypeptide of SEQ ID NO:2 isolated from monocyte wherein SEQ ID NO:2 is 80.4% identical to the claimed polypeptide of SEQ ID NO:6 (see attached sequence alignment of record). Adema et al. further teach methods of making and using monoclonal antibodies using polypeptide having amino acid sequences of SEQ ID NO:2 as immunogen using techniques such as hybridoma and recombinant technology. Furthermore, Adema et al. teach that the antibody can be fragment such as Fab, Fv, and can be attached to solid support including beads, and be included in units such as a kit (e.g. see pages 4-6). Moreover, Adema et al. teach that the antibody can be formulated into a pharmaceutical composition with pharmaceutically acceptable carriers and be presented in unit dosage form for parenteral administration, including subcutaneous administration and intravenous administration (e.g. see page 4 and 22-45).

As evidenced by Bost et al, antibodies can be specific and cross-react with the antigen. For example, antibodies which "cross-react" with IL-2 and HIV envelope protein, but establish that the binding of each protein is due to the presence of a homologous sequence in each protein in which 4 of 6 residues were identical (see entire document, but especially the Abstract and Discussion). Antibodies which bound either the HIV or IL-2 derived sequence did not cross-react with irrelevant peptides (e.g., "Results, page 579).

As further evidenced by Bendayan, the specific reactivity of a monoclonal antibody can be highly specific yet cross-react with antigens from different species or even distinct proteins not related to the original antigen (page 886, last paragraph).

Consequently, it was well known in the art at the time the invention was made that antibody binding of distinct proteins was indeed specific. Therefore, the reference antibody to SEQ ID NO:2 is specific to the instant polypeptide with SEQ ID NO:6.

Given that the claims are read as a purified antibody or fragment thereof instead of a complex containing antibody and antigen, the prior art antibody would anticipate the claimed invention.

Applicant's arguments, filed on January September 18, 2009, have been fully considered but have not been found persuasive.

Applicant argues that the instant claims distinguish from the prior art in that the claimed antibody is in complex with the antigen FDF03-S1. Thus, applicant argues the claimed antibody are not anticipated by the prior art since the Adema et al. do not teach FDF03-S1 consisting of amino acid sequence of SEQ ID NO:6.

This is not found persuasive for following reasons:

Given the high degree of sequence homology between the prior art polypeptide of FDF03 of SEQ ID NO:2 and instant FDF03-S1 consisting of SEQ ID NO:6, monoclonal antibody that binds to the prior art SEQ ID NO:2 would inherently bind shared regions of sequence identity of the instant polypeptide FDF03-S1 of SEQ ID NO:6.

Regarding the recited "wherein said antibody or fragment thereof is in complex with said DFD03-S1 polypeptide", it is once again noted that such recitation does not alter the structure of the claimed antibody. Claim scope is not limited by the wherein clause that does not limit a claim to a particular structure. See MPEP 2111.04. Here, given that the claimed antibody and the prior art antibody are identical or substantially identical in structure, the prior art antibody would inherently capable of being in complex with FDF03-S1 polypeptide that is 80.4% identical in amino acid sequence of the prior

art FDF03 polypeptide with SEQ ID NO:2. Applicant has not provided any objective evidence to show that the claimed antibody is structurally different from the prior art antibody.

As such, applicant's arguments have not been found persuasive.

9. Claim 7 is rejected under 35 U.S.C. 102(e) as being anticipated by Escobedo et al. (US 2002/0076761).

Escobedo et al. teach and claim a secreted protein having amino acid sequence of SEQ ID NO:21 wherein residues 65-291 of the SEQ ID NO:21 is 100% identical to the instant SEQ ID NO:6 (see claims 1-4 and the attached sequence alignment). Escobedo et al. further teach an antibody or fragment there of that binds SEQ ID NO:21 (e.g. see claim 5 and paragraphs [0081]-[0082]).

Given that the regions of the prior art protein and the instant SEQ ID NO:6 are 100% identical as discussed above, the prior art antibody would specifically bind the instant SEQ ID NO:6.

Regarding the recited "wherein said antibody or fragment thereof is in complex with said DFD03-S1 polypeptide", it is once again noted that such recitation does not alter the structure of the claimed antibody. Claim scope is not limited by the wherein clause that does not limit a claim to a particular structure. See MPEP 2111.04. Here, given that the claimed antibody and the prior art antibody are identical or substantially identical in structure, the prior art antibody would inherently capable of being in complex with FDF03-S1 polypeptide that is 80.4% identical in amino acid sequence of the prior art FDF03 polypeptide with SEQ ID NO:2. Applicant has not provided any objective evidence to show that the claimed antibody is structurally different from the prior art antibody.

Therefore, the reference teachings anticipate the claimed invention.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 7, 9, 18, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Escobedo et al. (US 2002/0076761) in view of Harlow et al. (Antibodies. A Laboratory Manual. 1988, pages 139-147 and 626-630) and Campbell (Monoclonal Antibody Technology. 1985 Published by Elsevier Science Publishers. Chapter I, pages 1-32, reference of record).

The teachings of Escobedo et al. have been discussed, supra.

The reference teachings differ from the claimed invention by not describing monoclonal antibody or antibody fragment, per se.

However, methods of making monoclonal antibody and fragment thereof and the advantage of using them in various immunoassays were well known in the art at the time the invention was made. For example, Harlow et al. teach that monoclonal antibodies can be made using hybridoma technique and that the advantages of monoclonal

antibodies include high specificity in binding, homogeneity, and their ability to be produced in unlimited quantities (see entire document, particularly pages 141-147). Further, Harlow et al. teach that the use of intact antibody in some immunochemical techniques can cause certain problems such as binding to Fc receptors and using antigen binding fragment, e.g. Fab, can overcome these problems; Harlow et al. teach methods of preparing antibody fragments (e.g. see pages 626-633). Campbell teaches methods of making antibodies and the advantages of using antibodies e.g. monoclonal antibody in basic research, diagnostics and therapeutic uses (see entire document, particularly pages 2-23). Further, Campbell teaches that it is customary now for any group working on macromolecule to both clone the genes coding for it and make monoclonal antibodies to it, sometimes without a clear objective for their application (e.g. see page28). Escobedo et al. clearly teach that polypeptide having amino acid sequence of SEQ ID NO:21 and one of skilled in the art would have been motivated to make antibody, e.g. monoclonal antibody, to SEQ ID NO:21 that is 100% identical to the instant SEQ ID NO:6.

It would thus have been obvious to the ordinary artisan at the time the invention was made to make monoclonal antibody and fragment thereof that specifically binds the prior art SEQ ID NO:21. The ordinary artisan would have been motivated to do so because antibodies against recombinant proteins can facilitate protein purification and monoclonal antibodies have the advantages of high specificity, homogeneity and can be produced in unlimited quantities. Given the teachings Escobedo et al. regarding the antibody that specifically binds SEQ ID NO:21 that is 100% identical to the instant SEQ ID NO:6, and the teachings of Harlow et al. and Campbell regarding methods of making and using monoclonal antibodies, the ordinary would have had a reasonable expectation of success of producing monoclonal antibodies or fragment thereof that binds prior art SEQ ID NO:21 and the instant SEQ ID NO:6.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Ram Shukla can be reached 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chun Dahle/
Examiner, Art Unit 1644